



146.1309

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: : PCT Date: 6/10/97  
JEAN-LUC DUBOIS :  
PCT No.: PCT/FR97/01024 :  
Filed: Concurrently Herewith :  
For: TRANSDERMIC...MEDICAMENTS :

600 Third Avenue  
New York N.Y. 10016  
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PRELIMINARY AMENDMENT

Asst. Commissioner for Patents  
Washington, D.C. 20231

Sir:

Please amend this application as follows:

IN THE CLAIMS:

Cancel claims 1 to 10 and add the following claims:

--11. A device for transdermic administration of two active ingredients (I) and (II) comprising a compartment (A) containing an adhesive polymer matrix containing active ingredient (I) and optionally at least one additive, a compartment (B) containing an adhesive polymer matrix containing active ingredient (II) and optionally at least one additive, each polymer matrix being rapidly covered with individual protective film (a) and a'), compartments (A) and (B) being supported on a peel-off protective film (b) at a distance of 1 to 10 mm apart.--

--12. The device of claim 11 wherein active ingredient (I) is a progestomimetic compound and active ingredient (II) is an estrogenic compound.--

--13. The device of claim 12 wherein the progestomimetic

compound is at least one compound selected from the group consisting of norethindrone, norgestimate, norgesterone, trimegestone, promegestone, (-) levonorgestrel, ST 1135, medroxyprogesterone, gestodone, dienogest, desogestrel, ketodesogestrel, norethisterone acetate and dimegestone.--

--14. The device of claim 2 wherein the estrogenic compound is at least one compound selected from the group consisting of 17 $\beta$ -estradiol, ethynyl estradiol, estrone and "equine origin" estrogen.--

--15. The device of claim 12 wherein the progestomimetic compound is trimegestone.--

--16. The device of claim 12 wherein the estrogenic compound is estradiol.--

--17. The device of claim 15 wherein the estrogenic compound is estradiol.--

--18. The device of claim 12 wherein compartment (A) contains an adhesive monolayer matrix of a silicone polymer containing trimegestone and optionally a plasticizer and component (B) contains an adhesive monolayer matrix of a 2-ethylhexyl acrylate and vinyl acetate copolymer containing estradiol and optionally an hydrophilic polymer.--

--19. The device of claim 11 wherein compartment (A) contains a two-layer adhesive polymer matrix with the first layer being a silicone polymer containing trimegestone and the second layer being a silicon polymer that adheres to the skin and compartment (B) contains an adhesive monolayer matrix of 2-ethylhexyl acrylate-

vinyl acetate copolymer containing estradiol and optionally a hydrophilic polymer.--

--20. A process for the preparation of a device of claim 11 comprising 1) manufacturing the matrix of compartment (A) by coating protective film (a) with a silicone adhesive polymer containing active ingredient (I)/, solvent and optionally at least one member of the group consisting of a hydrophilic polymer, an absorption promoter and a plasticizer, evaporating the solvent to obtain a set of matrix containing active ingredient (I)/protective film (a), colaminating the said set on a peel-off protective film (b'), and cutting a patch thereof of 5 to 20 cm<sup>2</sup>, 2) manufacturing the matrix of compartment (B) by coating protective film (a') with an adhesive polymer layer containing active ingredient (II), solvent and optionally at least one member of the group consisting of hydrophilic polymer, absorption promoter and plasticizer, evaporating the solvent to obtain a set of matrix containing active ingredient (II)/protective film (a') colaminating the said set on a peel-off protective film (b'') and cutting a patch thereof of 5 to 50 cm<sup>2</sup> and 3) peeling the peel-off protective film (b') from the patch of step 1 and transferring the set of matrix with active ingredient (I)/protective film (a) to peel-off protective film (b), peeling off protective film (b'') from patch of step 2) and transferring the set of matrix containing active ingredient (II)/protective film (a') to the peel-off protective film (b) at a distance of 1 to 10 mm to form the device comprised of compartments (A) and (B).--